

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference
P13612PC/PC/RO

FOR FURTHER ACTION

See Form PCT/IPEA/416

International application No.
PCT/GB2004/002695

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International Patent Classification (IPC) or national classification and IPC
A61B1/32, A61B1/31

Applicant
UNIVERSITY OF DUNDEE et Al.

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. sent to the applicant and to the International Bureau a total of 7 sheets, as follows:
 - sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

Date of submission of the demand

26.04.2005

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20.06.2005

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**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-29 as originally filed

Claims, Numbers

1-41 filed with telefax on 20.05.2005

Drawings, Sheets

1/18-18/18 as originally filed

- a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. The amendments have resulted in the cancellation of:
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

* IF item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

the entire international application.

claims Nos. 34-41

because:

the said international application, or the said claims Nos. 34-41 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for the said claims Nos. 34-41

the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

has not been furnished

does not comply with the standard

the computer readable form

has not been furnished

does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT
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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-33
	No: Claims	
Inventive step (IS)	Yes: Claims	1-33
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-33
	No: Claims	

2. Citations and explanations (Rule 70.7):**see separate sheet**

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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(SEPARATE SHEET)**

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Section III

Method claims 34 to 41 defines a method for treatment of the human or animal body by surgery. In particular, the method comprises the steps of inserting and moving a medical device into a body passage (rectum) and expanding the body passage for treatment or diagnostic purposes (see e.g. claim 41). This method, therefore, involves an interaction with the living human or animal body, and comprises a surgical action. Therefore no preliminary international examination is required for the subject-matter of these method claims (see Article 34 (4) (a) (i) PCT and Rule 67.1 (iv) PCT).

Section V

1. Reference is made to the following documents:
 - D1: WO 01/54568 A (STERILIS INC.) 2 August 2001
 - D2: KAKIZOE ET AL.: "Rectal expander-assisted Transanal Endoscopic Microsurgery in rectal tumors" SURGICAL LAPAROSCOPY AND ENDOSCOPY, vol. 8, no. 2, April 1998 (1998-04), pages 117-119, XP008035719
 - D3: US 2002/169363 A1 (HEROLD KAREN) 14 November 2002
 - D4: US-A-5 505 690 (PATTON MICHAEL T ET AL) 9 April 1996
2. The present invention relates to an expander for expanding a body passage. Such devices are well known in the art as exemplified by the above mentioned documents: Document D1 discloses an expander with tubular, distending balloons; D2 is a foldable plastic bottle; D3 concerns a speculum having dilating pivoting blades; and D4 discloses an expander having dilating blades which pivot in an end plate. None of the prior art documents, therefore, discloses or hints at expanding the body passage by controllably elastically deforming an expansion arm. Consequently, the subject-matter of claims 1 to 33 is novel and inventive and meets the requirements of Article 33 (1)-(4) PCT.

Section VII

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art

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disclosed in the documents D4 is not mentioned in the description, nor is this document identified therein.

2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
3. The description is not in conformity with the claims as required by Rule 5.1(a)(iii) PCT.

Section VIII

1. The embodiments of the invention described on pages 24 to 26 in relation to Figures 52 to 64 and 73 to 81 do not fall within the scope of the claims, since these embodiments do not have an elastically deformable arm. This inconsistency between the claims and the description leads to doubt concerning the matter for which protection is sought, thereby rendering the claims unclear, Article 6 PCT.

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CLAIMS

1. Medical apparatus adapted for location at least partly within a body passage, the apparatus having a leading end and an area for access from the apparatus into the body passage, at least part of the area spaced from the leading end, and the apparatus being controllably movable between collapse and expansion positions, for expanding the body passage, wherein the apparatus incorporates an expansion device comprising an expansion arm adapted to be moved between a collapsed position and an expansion position by controllably elastically deforming said expansion arm to expand the body passage.
- 15 2. Apparatus as claimed in claim 1, wherein the apparatus is adapted to be moved between the collapse and expansion positions in incremental steps.
- 20 3. Apparatus as claimed in any preceding claim, wherein the apparatus is controllably movable between fully collapsed and fully expanded positions, and is adapted to be moved to a position between the fully collapsed and fully expanded positions.
- 25 4. Apparatus as claimed in any preceding claim, wherein the apparatus is for use in transanal endoscopic microsurgery (TEM).
- 30 5. Apparatus as claimed in any preceding claim, wherein the collapse position of the apparatus is a rest position and the expansion position is a stressed position, and wherein the apparatus is adapted to move to the collapse position in the absence of an applied expansion force.

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6. Apparatus as claimed in any one of claims 1 to 4,
wherein the collapse position of the apparatus is a
stressed position and the expansion position is a further
5 stressed position, and wherein the apparatus is adapted
to move to the stressed position in the absence of an
applied expansion force.

10 7. Apparatus as claimed in any one of claims 1 to 4,
wherein the collapse position of the apparatus is a
stressed position and the expansion position is a rest
position, and wherein the apparatus is adapted to move to
the expansion position in the absence of an applied
collapse force.

15 8. Apparatus as claimed in any preceding claim,
comprising an actuating device including an activating
member adapted for moving the apparatus between the
collapse and expansion positions.

20 9. Apparatus as claimed in claim 8, wherein the
activating member is moveable relative to a remainder of
the apparatus.

25 10. Apparatus as claimed in claim 9, wherein the
actuating device comprises a screw mechanism including a
screw threaded member coupled to the activating member,
rotation of the screw threaded member adapted to move the
activating member relative to a remainder of the
30 apparatus, thereby moving the apparatus between the
collapse and expansion positions.

11. Apparatus as claimed in claim 9, wherein the
actuating device comprises a ratchet mechanism including

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a slider coupled to the activating member and a locking member, movement of the slider relative to the locking member adapted to move the activating member relative to a remainder of the apparatus, thereby moving the apparatus between the collapse and expansion positions.

5 12. Apparatus as claimed in any one of claims 8 to 11, wherein the actuating device comprises a motor for moving the activating member.

10

13. Apparatus as claimed in any preceding claim, comprising a lock for locking the apparatus in a desired position.

15

14. Apparatus as claimed in any preceding claim, wherein the access area extends from the leading end and part way along a length of the apparatus.

20

15. Apparatus as claimed in any preceding claim, comprising a guide member, the guide member adapted for location at least partly within the body passage.

25

16. Apparatus as claimed in claim 15, wherein the guide member defines the leading end and the access area of the apparatus, and wherein said at least part of the access area is spaced from the leading end along a length of the guide member.

30

17. Apparatus as claimed in either of claims 15 or 16, wherein the access area is an aperture in a wall of the guide member.

18. Apparatus as claimed in any one of claims 15 to 17, wherein a distance between the access area and a trailing

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end of the guide member is minimised, to facilitate access through the opening.

19. Apparatus as claimed in any one of claims 15 to 18,
5 wherein the access area is an elongate opening, of a greater dimension in a direction along a main axis of the guide member than in a direction around a perimeter of the guide member.

10 20. Apparatus as claimed in any one of claims 15 to 19, wherein the access area is an opening extending around at least half of a perimeter of the guide member.

15 21. Apparatus as claimed in any preceding claim, including an inlet at a trailing end thereof for access into the apparatus and to the access area.

20 22. Apparatus as claimed in any one of claims 15 to 21, wherein the expansion arm is mounted on and extends longitudinally with respect to the guide member.

25 23. Apparatus as claimed in any preceding claim, wherein the expansion arm is adapted to adopt a curved shape when in an expansion position.

24. Apparatus as claimed in any preceding claim, wherein the expansion arm is of a shape memory alloy.

30 25. Apparatus as claimed in any preceding claim, wherein the expansion arm is adapted to be moved to the expansion position by heating the device above a transition temperature of the shape memory alloy.

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26. Apparatus as claimed in any one of claims 9 to 25, wherein the expansion device is movable to the expansion position in response to a force applied by the actuation device.

5

27. Apparatus as claimed in any preceding claim, wherein the expansion device comprises at least one inflatable element, adapted to be inflated to move the apparatus to the expansion position.

10

28. Apparatus as claimed in any preceding claim, wherein the expansion device comprises a plurality of inflatable elements, the elements axially spaced with respect to a main axis of the apparatus.

15

29. Apparatus as claimed in claim 27 or 28, wherein the/each elastically deformable expansion arm is coupled to a respective inflatable element.

20

30. Apparatus as claimed in claim 27 or 28, wherein the/each expansion arm is coupled between at least two respective axially spaced inflatable elements.

25

31. Apparatus as claimed in any one of claims 15 to 30, comprising a flexible cover extending between the expansion device and the guide member, for preventing any part of the body passage from damage during movement of the expansion device between the collapse and expansion positions.

30

32. Apparatus as claimed in any preceding claim, wherein the expansion device provides a force-feedback to an operator during movement between the collapse and expansion positions.

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33. Apparatus as claimed in any preceding claim,
comprising a device for measuring an expansion force
exerted on the body passage during movement of the
apparatus between the collapse and expansion positions.

34. A method of providing access to a body passage, the
method comprising the steps of:

10 inserting a medical apparatus at least partly into a
body passage with the apparatus in a collapse position;

controllably moving the apparatus from the collapse
position to an expansion position by controllably
elastically deforming an expansion arm, to expand the
body passage; and

15 accessing the body passage through an access area of
the apparatus, at least part of the access area being
spaced from a leading end of the apparatus.

35. A method as claimed in claim 34, comprising exerting
20 an expansion force on the medical apparatus following
insertion into the body passage, to move the apparatus to
the expansion position.

36. A method as claimed in claim 34, comprising exerting
25 a collapse force on the medical apparatus, to move the
apparatus to the collapse position and to restrain the
apparatus in the collapse position for insertion into the
body passage, and subsequently releasing the collapse
force, whereupon the apparatus moves to the expansion
30 position.

37. A method as claimed in any one of claims 34 to 36,
comprising controllably moving the apparatus from the

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expansion position to the collapse position and removing the apparatus from the body passage.

38. A method as claimed in claim 37, further comprising
5 rotating the apparatus relative to the body passage,
reinserting the apparatus into the body passage and
returning the apparatus to the expansion position.

39. A method as claimed in any one of claims 34 to 36,
10 comprising returning the apparatus to the collapse
position, rotating the apparatus within the body passage,
and then returning the apparatus to the expansion
position.

15 40. A method as claimed in any one of claims 34 to 39,
comprising viewing the body passage through the access
area.

41. A method as claimed in any one of claims 34 to 40,
20 comprising conducting a diagnostic procedure on the body
passage.

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